PSJ3

Exhibit 674I

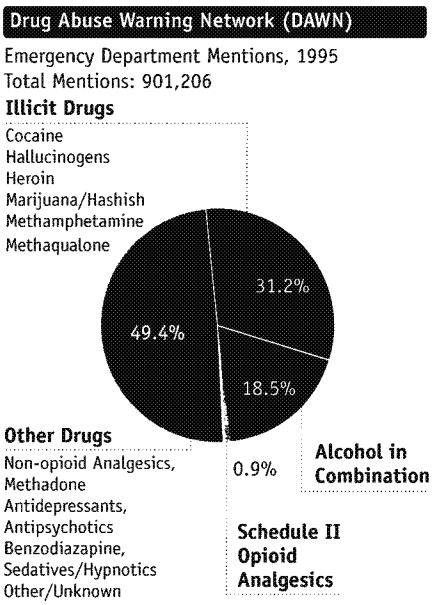
level I'm willing to believe you, but on a visceral level I just can't believe that you can take these medications and not get addicted,'" says Richard Payne, M.D., chair of Pain and Palliative Care Services at Memorial-Sloan Kettering Cancer Center.

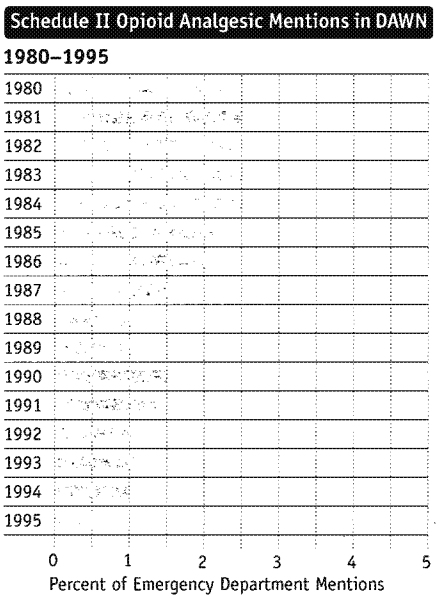
A common misperception is that patients are addicted when they become physically dependent upon opioids to control pain. Pain-management experts are eager to correct this confusion. *Addiction*—or psychological dependence—is a behavioral disorder characterized by compulsive seeking of mood-altering drugs and continued use despite harm. *Physical dependence* is a normal response of the body to a substance characterized by signs of withdrawal if drug use is stopped.

"Physical dependence is an expected result of opioid therapy. Addiction among patients who use opioids for pain management is exceedingly rare," says David Joranson, M.S.S.W., senior scientist and director of the Pain and Policy Studies Group (PPSG) at the University of Wisconsin–Madison. "It's so important to be clear about these terms," Joranson says.

State Cancer Pain Initiatives

"Pain management is a relatively young field," says Joranson, who came to the PPSG from the Wisconsin Cancer Pain Initiative (WCPI) and the state's controlled substances board (CSB). Pain management emerged as a separate science in the mid-1980s, along with the development of state initiatives to improve cancer pain treatment. Wisconsin's initiative was developed in response to the 1986 congressional debate over the Compassionate Pain Relief Act, which would have given heroin limited legal use. The CSB opposed heroin legalization because legal pain medications like morphine were just as effective for pain treatment as heroin, but underused by physicians. After helping to defeat the heroin bill, the CSB started the WCPI, which made cancer patients' access to existing, legal pain medications one of its missions. Now every state has a cancer pain initiative.





Source: University of Wisconsin Pain and Policy Studies Group/WHO Collaborating Center

"Triplicate" Laws and the War on Drugs

"The whole discussion about addiction in this country has made people with pain the victims of the 'war on drugs,'" says Kathleen Foley, M.D., a neurooncologist at Memorial-Sloan Kettering Cancer Center and director of the Project on Death in America.

Regulatory focus on diversion of prescription drugs to illicit uses has hampered pain management by prompting some states to enact restrictive prescription monitoring laws and regulations. These vary from state to state, but one approach requires physicians to use a special state-issued form when prescribing controlled substance—an approach commonly known as a "triplicate" law because most multiple-copy forms are in triplicate. Of the 17 states that have prescription-monitoring programs, seven still require special forms (the others have converted to electronic monitoring). Programs in these seven states monitor prescriptions for more than one-third of the U.S. population.

Payne, who is licensed to practice medicine in New York, Ohio, and Texas, cites "triplicate laws" as the number-one barrier to better pain management. The method is invasive: "There's the sense that you're being watched," Payne says. Joranson notes that many physicians in "triplicate" states avoid the hassle by not even requesting the forms.

The result for patients is reduced access to pain treatment. But the data are clear (as the charts above illustrate) that for many years the abuse of morphine—the standard treatment for cancer pain—has remained essentially unchanged.

Increasing awareness of the need for better pain treatment recently has spurred dialogue between the medical community and the regulatory and law-enforcement communities. State-level policy makers are participating in this dialogue and working to improve pain treatment by

- removing legislative barriers to pain treatment
- relieving physicians' fears of being sanctioned for appropriate prescribing, and
- creating a policy environment for better pain treatment. ■

Removing Legislative Barriers to Pain Treatment

Out of fear of abuse and diversion, and to hold the lid on exploding medical costs, states have built legal hoops that have physicians and patients scrambling. For example, some state laws

- limit patients' ability to get a prescription for opioids filled if it is written by a physician practicing in another state
- put absolute per-month, dollar-amount restrictions on prescription-drug reimbursement.

If you were, for example, a cancer patient living in a state where the above laws apply, you could run into the following trouble:

- You have found a cancer specialist in another state, and that physician is treating your cancer, including the pain it causes, giving you hope of returning to work, regaining your life—but you can't get your prescriptions filled in your hometown.
- You are a patient with advanced cancer. To control your pain, you need 400 mg of morphine per day—a standard dose for chronic cancer pain treatment. But your prescription plan has a limit of $1,000 per year. You must pay the rest out of pocket. (By contrast, your outpatient intravenous chemotherapy is fully reimbursed.)

"Morphine is among our cheapest drugs," says Joanne Lynn, but 400 mg per day might cost roughly $7,500 per year. With a prescription plan reimbursing only $1,000 of that, the patient is left to pay $6,500, a high out-of-pocket amount for many individuals to cover. Those who are poor or uninsured might be able to afford even less.

> "States can include language in their controlled-substances laws that recognizes the treatment of pain as a public-health issue and frames their policies to provide appropriate treatment for chronic pain."
>
> Kathleen Foley, M.D.,
> Director, Project on Death in America

Many states are revising their laws to eliminate undue restrictions on pain management while continuing to protect public health.

States Convert to Electronic Prescription Monitoring

Some of the most populous states—California, New York, Illinois, and Texas—are converting from triplicate forms to "electronic data transfer" (EDT) monitoring, whereby pharmacies use telephone lines to transfer prescription information to monitoring agencies, making the monitoring system less invasive, advocates say.

Those working in California for pain policy reform hope the conversion will be finished within a year. Betty Ferrell, Ph.D., FAAN, chair of the Southern California Cancer Pain Initiative, is optimistic: "The Initiative is in contact with all the parties involved in making that happen."

New York's recent conversion to EDT still requires physicians to use a special prescription form. Another revision New York has passed, and other states are considering, amends controlled-substances laws to state that one of their primary intents is to foster legitimate medical opioid use.

Kathleen Foley thinks this is one of the most important contributions states can make toward fostering more balanced attitudes about pain treatment. "States can include language in their controlled-substances laws that recognizes the treatment of pain as a public-health issue and frames their policies to provide appropriate treatment for chronic pain," Foley says.

The Role of Pain-Treatment Legislation

Twenty-five states have adopted pain-treatment legislation. Often called "intractable pain treatment acts" (IPTAs), these laws are designed to reduce physicians' fear of sanctions by providing immunity from discipline, though not from investigation, for physicians who prescribe opioids for "intractable" pain.

The PPSG, however, points out that IPTAs put undue restrictions on medical decision-making and patient access to pain medicine by

- defining medical use of opioids as a "therapy of last resort"
- implying that opioids can be used for pain only in cases where the cause of pain cannot be removed
- requiring evaluation of the patient by a second physician
- excluding pain patients with a history of drug abuse (Joranson, 1997).

Once enacted, such restrictions are difficult to rescind or adapt to advances in pain-management science.

IPTAs also carry a semantic conundrum. "Labeling pain 'intractable,'" Joranson says, "implies that medicine can do nothing to alleviate the pain. But in fact chronic pain is generally treatable. Existing treatments, including medications, can relieve most if not all pain."

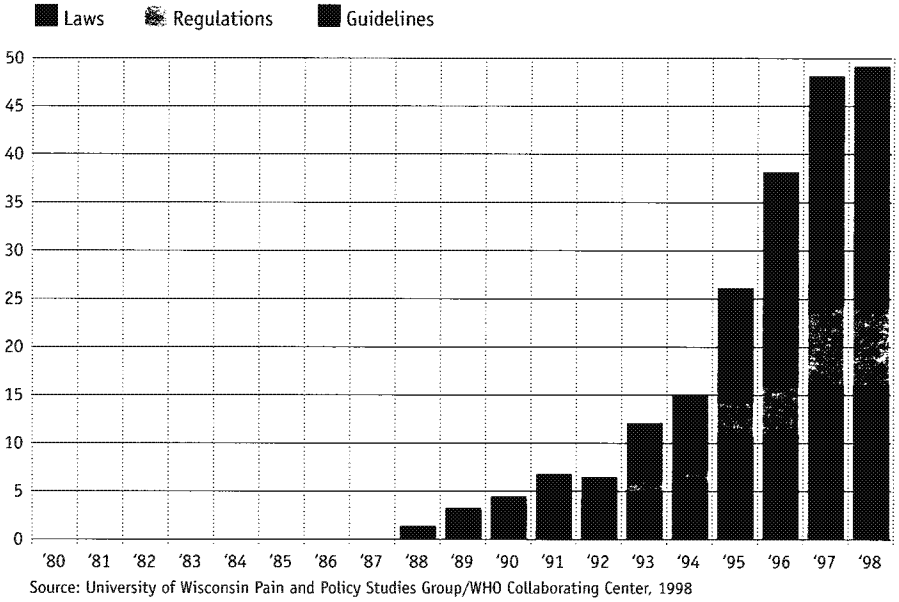
The Role of Task Forces, Pain Commissions, and Coalitions

New York's legislative reform was spurred by a series of recommendations made last year by the state Ad Hoc Committee on Pain Management, commissioned in 1997 by the Department of Health. The committee's January 1998 report is an example of comprehensive reform that crosses state-level policymaking boundaries, with input from the medical, nursing, hospital, nursing home, home care, hospice, law enforcement, and legal communities (DeBuono, 1998). "State pain commissions can do a wonderful job of uniting all these parties," says June Dahl, Ph.D., director of the Wisconsin Cancer Pain Initiative.

The New York Department of Health also has initiated a coalition, funded by The Robert Wood Johnson Foundation's Community-State Partnerships to Improve End-of-Life Care Program (C-SP). It will hold grassroots pain-management education sessions at churches, schools and other community-based locations. Thirteen of 17 state coalitions funded thus far by C-SP have identified pain-management as a major problem in end-of-life care.

Other initiatives around the country tackling pain policy as part of end-of-life-care reform are being funded in part with public support. In addition, some cancer pain initiatives are expanding their concern to other types of pain, in effect becoming general pain initiatives. ■

State Pain-Related Policies in Effect, 1980–1998



Source: University of Wisconsin Pain and Policy Studies Group/WHO Collaborating Center, 1998

For the complete New York Ad Hoc Committee on Pain Management report and New York's new controlled substances law, see the Department of Health website: **www.health.state.ny.us/nysdoh**

For the American Pain Society's Quality Improvement Guidelines for the Treatment of Acute Pain and Cancer Pain, visit the APS website: **www.ampainsoc.org/pub**

The Mayday Pain Resource Center (MPRC) is a central source that collects a variety of materials including pain assessment tools, research instruments, materials on patient education and quality assurance, and other resources. MPRC publications are available through their website: **www.mayday.coh.org**

Bringing Better Pain Management into "Ordinary Medical Practice"

Fear of regulatory scrutiny continues to be the most common reason physicians give for not providing adequate treatment for chronic pain (Martino 332). Potent and persistent, this fear is handed down from one generation of medical residents to the next. "Research shows that the way physicians really learn is not through books but through one-to-one contact. Generations of care givers have been trained to stigmatize opioids," says Sandra Johnson, J.D., L.L.M., provost of St. Louis University and a specialist in medical ethics and end-of-life care issues. Physicians' fear of regulatory reprisal logically calls for better communication between physicians and regulators.

To this end, the Oregon Board of Medical Examiners holds workshops with physicians to clarify its stand on prescribing practices and to urge physicians to use the board's standards in their practices. Sometimes these workshops actually boil down to one-to-one contact: "Last weekend I went down to southern Oregon and gave a talk that drew literally a couple of people," says Board Director Kathleen Haley, J.D. "A couple of people is OK in my book because one was a chief of staff, and he oversees hundreds of physicians, and those physicians see hundreds and hundreds of patients."

Joranson, who has educated members of every state medical board about the false assumptions commonly held about opioids, believes that the risk of regulatory scrutiny is declining, and that it is now more a perceived than real threat for most physicians. Physicians treating terminal cancer pain are rarely investigated. But investigation is time-consuming and subjects the target physician to social suspicion that can hurt a carefully built practice.

Easing Physicians' Fear Through Pain-Treatment Guidelines

Some medical boards are attempting to ease physicians' fear of investigation by adopting pain-management guidelines. Those working to ease tensions between regulators and clinicians believe pain-treatment policy must integrate pain management into "ordinary medical practice," as Joranson puts it—rather than treating it as a separate medical practice with its own (usually tighter) restrictions, as IPTAs do. Because state medical boards—not legislatures—are charged with ensuring citizens receive competent medical care, many working in pain policy reform say pain-treatment guidelines are a key to reducing physicians' fear of sanctions. The Federation of State Medical Boards' model guidelines on the use of opioids in pain management, released in May 1998, are often cited as an example of progressive pain policy because they

- accept opioids' medical legitimacy
- reject quantity and chronicity of prescribing as regulatory measurements of good medical practice
- state that the board will not discipline a physician for failing to adhere strictly to the guidelines if good cause is shown for deviation.

For the complete model guidelines, see the FSMB website: **www.fsmb.org/pain.htm**

Many pain policy reformers favor the model guidelines over IPTAs because the model guidelines

- do not carry IPTAs' undue restrictions (see p. 5)
- are more flexible than laws and more relevant to clinical practice, thus better able to keep up with advances in pain management science.

Johnson, for one, has written articles extolling pain treatment acts' benefits, but she, too, prefers progressive medical-board guidelines. The DEA has endorsed the FSMB model guidelines, and the Kansas medical board adopted them immediately.

But guidelines in general also have their drawbacks: they depend upon board willingness to enforce them, and they can change with changes in board attitude and membership.

Investigating Undertreatment, Not Just Overprescribing

Susan Tolle, M.D., a practicing internist who directs the Oregon Center for Ethics in Health Care, would like to see boards define quality indicators for pain undertreatment. "At the moment, physicians in other states can get into trouble only by *writing* prescriptions. But refusing to write *any* also falls into the scope of bad practice," Tolle says.

The Oregon medical board recently announced its intention to discipline a physician for failing to give six seriously ill or dying patients adequate pain medication. However, making investigation of undertreatment a policy may be premature until boards and physicians communicate more clearly about actual expectations regarding opioid use. In any case, some experts believe discipline should emphasize education, not punishment: "To take them to task for something they were never educated properly about in the first place is too harsh," says June Dahl.

Oregon has also established palliative-care teams that model good pain-management practices "for everyone from residents up to established senior faculty," Tolle says. "Someone needs to teach how to take the guidelines and make them come alive at the bedside."

"Major emphasis has to be placed on assessment. You can't treat what you don't know about."

June Dahl, Ph.D., Director, Wisconsin Cancer Pain Initiative

Strengthening Pain Assessment: A Role for Nurses

Just as nurses assess temperature, blood pressure, pulse rate, and respiration, assessing patients' pain levels on a zero-to-10 scale, where zero indicates absence of pain, is the first step toward recording the strength and duration of a patient's pain. Without such a record, accountability is impossible.

"People would never be allowed to lie around in a hospital bed with a fever of 105, but a lot of people lie around in the hospital with pain scores of 9 out of 10," Dahl says. "Major emphasis has to be placed on assessment. You can't treat what you don't know about."

Assessing pain as the "fifth vital sign" was the foremost action-item endorsed by 30 leaders of national nursing organizations at a symposium on "Peaceful Death" late last year. The American Academy of Nursing has committed to stimulating state licensing agencies to develop a fifth-vital-sign quality indicator for site-evaluations.

Nurses are likely leaders in implementing fifth-vital-sign programs at their institutions. Nurses are also looking toward the release of the Joint Commission on the Accreditation of Healthcare Organizations' new pain treatment guidelines. The new guidelines will include hospitals, home care, ambulatory care and behavioral health facilities. They are now in review for release next year.

A Role for Pharmacists

The Mississippi Board of Pharmacy (BOP) is working with the state's medical and nursing boards on a team approach to palliative care that can be replicated across the country. Hospice medical directors and pharmacists make rounds together, with the physician developing plans of care and the pharmacist permitted to implement the plan. Mississippi Medicaid is the first in the nation to pay pharmacists to work with physicians to assist in managing patient care plans. "In a hospice atmosphere, you don't have the physician all the time. The most easily accessible medical professional is the pharmacist," says Mississippi BOP Director William "Buck" Stevens. He hails this model as "a bridge to enable everybody to focus on patients."

- encourage states to move away from declaring patients "terminal"—usually a requirement for hospice admission—and toward a definition of "life-limiting illness," which would permit hospice admission earlier in treatment of a slow-moving terminal illness
- ensure patients' access to early, aggressive pain management by providing timely referral to hospice.

States can

- provide funding and support for their cancer pain initiatives, many of whose staff cite lack of funding as a major impediment to their work
- through licensing agencies, develop state pain-management standards for nursing homes
- with the influence of state attorneys general and agency directors, urge the federal Health Care Financing Administration (HCFA) to develop standards and provide adequate funding
- guarantee Medicaid funding of palliative care in a variety of settings
- create and fund media campaigns to educate citizens to expect and ask their physicians for better pain management
- include a pain management expert on the state medical board and in the office of professional conduct, to conduct a pre-review
- provide protection for pharmacies located in neighborhoods with high risk of robbery
- encourage professional and trade associations, including managed care organizations, to promote pain management. ■

For the complete JCAHO Proposed Standards for Pain Assessment and Treatment, visit their website at **www.jcaho.org/pubedmul/publicat/pat/pat_frm.htm**

Creating a Positive Environment for Better Pain Management

There are many ways in which medical professionals and policy makers alike can help create a positive environment in which pain-management policy reform can more easily occur.

Medical professionals can

- persuade state licensing agencies, health departments, aging offices, and other officials to collaborate on pain management quality indicators
- urge state-supported medical schools and teaching hospitals to include better and more accurate pain management information in curricula and training

Public Education

Bibliography

Many reformers believe improving pain management ultimately depends upon the public's willingness to demand it. The message that "pain can almost always be controlled" has reached Oregon citizens through strategic media-relations campaigns coordinated by reformers like Tolle. She regularly meets with reporters regarding progress on Oregon's policy reform successes in end-of-life care—of which pain-management reform is a primary aspect. "The primary force for change is public education," Tolle says. "Patients need to demand better pain treatment."

To "get the issue on the public radar," says Jim Guest, executive director of the American Pain Foundation, state agencies can

- fund print-media and advertising campaigns through the health department
- require health plans to distribute pain-management information and end-of-life care to all enrollees
- develop leaflets for doctor's-office distribution about "How to describe your pain," "How to talk to your doctor about pain," and "Pain can usually be controlled"
- declare a Pain Awareness month, week, or day
- disseminate consumer information through chapters of nonprofit groups, public libraries, and local community groups.

"What's missing for me is that consumers are not outraged and out there demanding better care," Joan Teno says. "We need to educate them that you can have your pain managed to the level that you desire." ■

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State Initiatives in End-of-Life Care

Issue 14, May 2002

Focus: Pain Management—An Update

The Need for Balance in Controlled Substances Policy

Krkistin Petersen

INSIDE

Comprehensive pain management is dependent upon the powerful painkillers known as opioids, but it is not limited strictly to their use. Hospice workers like Ailene Josephs (above, massaging the back of an end-stage breast cancer patient enrolled at Forbes Hospice/West Penn Allegheny Health System, Pittsburgh) know that opioid therapy is one of many modalities used to treat the different types and degrees of pain experienced at the end of life. They also know that opioid therapy, when tailored to the individual patient, can indeed be as caring and as life-enhancing as the massage shown above.

Unfortunately, one result of the public effort to prevent drug diversion is that legitimate pain patients are being prevented from access to opioids. A recent Brown University study found that 40 percent of nursing home residents experience moderate to excruciating daily pain that goes inadequately treated for two to six months after they first report it to staff (see p. 2). In addition, fears and misperceptions about opioids and addiction still abound among doctors, patients, and policymakers alike.

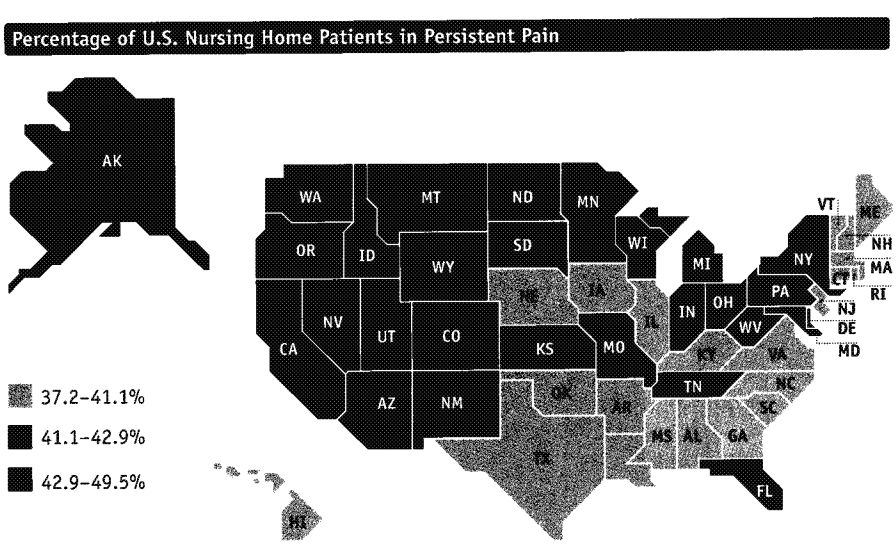
Effective Pain Control: Still Elusive for Many Dying Americans

By the year 2020 nearly half of all Americans facing the end of life will be nursing home residents. Currently, nearly half of Americans living into their eighties spend some time in a nursing home. For 40 percent of nursing home residents, here's what that means: living with "moderate" to "excruciating" daily pain that goes inadequately treated two to six months after they first report it to staff.

This disturbing finding is one result of a Brown University study that appeared in the April 25, 2001, issue of the *Journal of the American Medical Association*. The study was the first to take a comprehensive, data-based look at pain among elderly nursing home residents nationally, and it finds that, overall, pain among the more than 2.2 million Americans living in nursing homes is epidemic and poorly treated. What's more, the researchers believe the findings *underestimate* these residents' pain burden, since the findings are based on nursing home staff reports, and staff generally underreport residents' pain.

Nursing home residents aren't the only ones suffering pain at the end of life. Even cancer patients still find palliative care elusive. A recent Institute of Medicine study found that of the half-million Americans who die from cancer each year only about half receive any pain and symptom management at all.

What's behind the lack of pain management at the end of life?—persistent, mistaken beliefs about the class of controlled substances known as *opioids*.



Source: Brown University School of Medicine, Center for Gerontology and Health Care Research

This brief follows up our 1999 brief about the state of pain management policy as it pertains to end-of-life care. Some gains have been made in the past five years or so. For example, the DEA Office of Diversion Control reports that prescriptions dispensed for all common opioids from 1996 to 2000 increased by 23 percent. This is a sign that medical use of opioids is increasing and perhaps that more pain is being treated.

But chronic pain patients continue to have unduly limited access to opioids. Chronic pain—whether malignant or nonmalignant— remains a major public health concern, with more than 50 million American sufferers. Recently, sensational media reports of cases of diversion and abuse of a relatively new long-acting pain medication, OxyContin (OC), have renewed policymakers' concern about increasing medical use of opioids: a congressional hearing was held on the matter in December 2001 and an FDA hearing in January 2002.

But those familiar with drug enforcement and controlled substances policy—including DEA Administrator Asa Hutchinson—are calling for a balanced attitude toward this latest crisis and toward drug enforcement policy in general. This brief will explore the diversion and abuse of OC and those calls for balance. It will take a look at a historic joint statement advocating a balanced policy, issued in October 2001 by the DEA, pain organizations, and pain policy groups. Finally, this brief will summarize other recent advances in pain policy that have been implemented, or that need to be implemented, in order to improve the care of Americans facing the end of life. ■

Opioid Diversion: A Renewed Call for a Balanced Drug Policy

Tracking the Damage of Today's "Drug du Jour"

The opioid making headlines recently is the long-acting painkiller OxyContin (OC), recently the subject of hearings before a House Appropriations subcommittee and the FDA. When it comes to "Oxy," it's hard to get a clear picture of the toll the abuse and diversion problem has taken. Lots of numbers appear in the media:

- The *Philadelphia Inquirer* reported that oxycodone, the opioid in OC, was linked to 41 deaths in 2000 and 39 deaths in the first half of 2001.
- *USAToday* reported 268 deaths in 1999 due to oxycodone overdose.
- *National Public Radio* reported 42 oxycodone overdose deaths in western Virginia from 1997 to 2001.

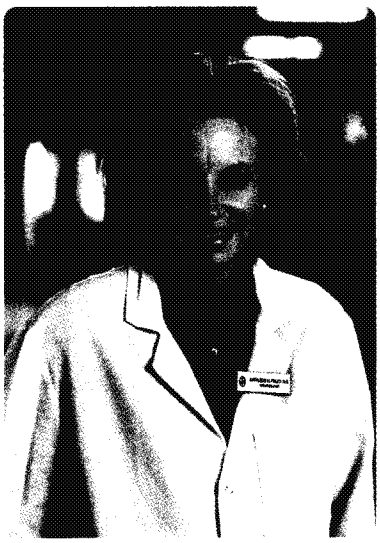
The OC diversion problem began to make headlines in 2000. Since then its manufacturer, PurduePharma, has maintained that it is difficult to quantify the number of casualties of the drug's abuse. "Any death with oxycodone present in the blood is called an 'OxyContin death.' But there are 59 products on the market with oxycodone in them," says PurduePharma spokesman Robin Hogen, adding that many of the overdose cases involved alcohol and other drugs. Media reports sometimes confuse oxycodone with OC, leading to further confusion.

The best available data on U.S. drug abuse deaths comes from the Drug Abuse Warning Network (DAWN). DAWN data are compiled from medical examiners reporting from 14 U.S. cities. DAWN's most recent overdose data available put the number of U.S. heroin- and cocaine-related deaths at more than 9,700 per year, more than 30 times greater than the oxycodone-related deaths. Although estimates of oxycodone deaths vary widely, for this comparison, one of the high estimates—262—was used. OC deaths would be, of course, a subset of total oxycodone deaths. One issue clearly revealed in the DAWN data is the prevalence of polydrug use and combined drug and alcohol abuse, which make attributing any death to one particular drug quite problematic. A further complication in assessing DAWN data with respect to OC is that OC diversion has been concentrated in rural areas and DAWN reports from urban centers. Still, the DAWN death reports for heroin and cocaine far exceed the OC-related death estimates, contrary to media reports. "One journalist wrote, 'The OxyContin abuse problem is greater than that of heroin and cocaine,'" says June Dahl, PhD, director of the Wisconsin Cancer Pain Initiative. "This was his interpretation of the DAWN data. The media have at times been very irresponsible."

> "It's not cancer pain patients who are dying of OxyContin overdose; sadly, it's people abusing drugs who are dying."
>
> Kathleen Foley, MD,
> Attending Neurologist,
> Pain and Palliative Care Service,
> Memorial Sloan-Kettering Cancer Center

Dying Patients Are Not Involved

Despite all the confusion surrounding the abuse of OC, two things are clear. First, OC is indeed being diverted and abused to the point that it is now the "street drug of choice" in some areas, especially on the rural Appalachian ridge from Maine to Kentucky, and more recently in Philadelphia. Second, OC is not yet widely prescribed to fight cancer pain—though pain physicians agree that it is an important and appropriate drug for that use. Couple these two facts and it's clear that patients having pain at the end of life have nothing to do with this latest crisis.



Pain specialists and pain policy experts are concerned that mistaken and sensationalistic media reports will create a backlash among policymakers against treating pain, which they say has become at least as much a public health epidemic as drug abuse, with 50 million adult American sufferers "and an untold number of children," according to Russell K. Portenoy, MD, chair of the Pain Medicine and Palliative Care department at Beth Israel Medical Center in New York.

Moreover, they stress that prescription drug diversion is a criminal act that should be addressed without adverse effect on medical practice and treatment of pain. "It's not cancer pain patients who are dying of OxyContin overdose; sadly, it's people abusing drugs who are dying," says Kathleen Foley, MD, a preeminent neurooncologist at Memorial Sloan-Kettering Cancer Center.

Continues on page 4

Examples of Balanced and Unbalanced Policy

Examples of Balanced Policy

- Police pursuing organized crime rings involved in prescription-drug thefts and pharmacy burglaries
- Law enforcement identifying physicians and pharmacies who are prescribing or dispensing drugs for addicts or for resale
- States moving toward electronic prescription monitoring to prevent doctor-shopping, forgery, and diversion
- The agency that oversees a state's Medicaid program investigating for doctor-shopping any patients receiving controlled substance prescriptions from more than one physician
- State legislatures making the theft of a prescription pad a felony offense
- State medical boards adopting the Federation of State Medical Boards' model guidelines for the treatment of pain (**www.fsmb.org/pain.htm**)

Examples of Unbalanced Policy

- States restricting dispensation of opioid drugs to a limited number of pharmacies
- States limiting opioid prescribing privileges to pain specialists, of whom there are only 1,200 in the country
- States, such as California, adhering to multiple-copy prescription form programs, which are time-consuming and which discourage physicians from treating pain because of fear of oversight (for more about electronic monitoring versus special prescription forms, see p. 6)
- States adopting Intractable Pain Treatment laws, which place undue restrictions on medical decision making and patient access by defining opioids as treatment of last resort and requiring second opinions for pain patients
- Law enforcement officials or narcotics agents "going fishing"—that is, investigating pharmacy or physician records without specific evidence that diversion is occurring

OC Is Not Most Commonly Abused Opioid

"Proportionately, diversion [of prescription opioids] is in line with medical use. What's out of proportion is the drug-enforcement response. They have not stopped to look at the data," says Betty Ferrell, PhD, FAAN, a nurse and pain policy researcher at the City of Hope Medical Center who chairs the Southern California Cancer Pain Initiative (SCCPI).

According to the most recently available annual data (1997) published by the U.S. government's Drug Abuse Warning Network (DAWN), oxycodone in all forms was mentioned in 2 percent of all prescription medication–related emergency department visits in which abuse was suspected. This ranked oxycodone—not OC—fourteenth on the list of drugs of abuse—well behind such well known medications as Vicodin (an opioid), Valium, acetaminophen, ibuprofen, and even aspirin. With 39 preparations of oxycodone besides OC on the market, that puts OC even lower on the list.

"Drug abuse is serious—it affects human lives and families. But we have to realize that prescription drug abuse is a cyclical phenomenon—that it comes and goes," says David Joranson, MSSW, senior scientist and director of the Pain and Policy Studies Group (PPSG) at the University of Wisconsin–Madison, which conducts annual studies of pain policies. "Looking back, you can see outbreaks of abuse that are successfully addressed. Also, there is a certain constant level of drug abuse that's going to affect the prescription drugs like the opioids. Addressing abuse of prescription pain medications requires a balanced approach to drug policy."

Pharmacists agree. "Clearly, the time has come for . . . the development of a more effective but balanced approach to opioid regulation," wrote David Brushwood, JD, RPh, a professor at the University of Florida College of Pharmacy, in the October 2001 newsletter of the National Association of Boards of Pharmacy (www.nabp.net). "We hold the key to the medicine chest and, while we need to lock the chest when inappropriate requests are made of us, we need to open the chest when legitimate patients in need of pain relief seek our products and services."

What Is Balanced Pain Policy?

Joranson says balanced policy identifies and addresses the sources of diversion without interfering with medical practice and patient care. He compares opioid prescribing to a pipeline, and says diversion can occur when

- the proper outlets in the pipeline malfunction, such as improper prescribing or dispensing. This has been shown to be a fringe activity of a very few unscrupulous physicians or pharmacists—and is a primary target of law enforcement.
- the pipeline is punctured from the outside, resulting in leaks: doctor-shopping, prescription forgery, and theft. These sources make up a major part of diversion—but are more difficult for law enforcement to address.

"The litmus test for balanced policy and enforcement is to ask these two questions: 'Does the policy get directly to the source of diversion?' And, 'Does it interfere with medical practice or patient care?' If the answer to the first is Yes and to the second is No, then the policy is balanced," Joranson says.

Continues on page 8

DEA Teams with Pain Groups on Historic Statement

On October 23, 2001, DEA Administrator Asa Hutchinson announced that his agency and 21 leading health care organizations had endorsed a statement supporting medical use of opioids (see excerpt, below). The document articulated no new DEA position except for the administrator's willingness to align himself with pain groups. "It certainly is without precedent that the DEA would join with key health care and pain organizations to reiterate existing policy," says the PPSG's Joranson. "But policy is worth nothing unless it's communicated, understood, and observed." Adds Purdue's Hogen: "The problem is not in Washington, the problem is in small towns hundreds of miles away, where there are DEA agents terrorizing pharmacists and physicians for dispensing opioids. The enlightened attitude of the DEA administrator needs to trickle down to DEA agents on the front lines."

DEA staff say the agency has worked hard to change physician and pharmacist fears. The DEA has organized seminars for practitioners about appropriate prescribing and has endorsed the Federation of State Medical Board Guidelines (see p. 7). Pat Good, chief of the DEA's Liaison and Policy Section, calls physicians' fear of DEA scrutiny "a false perception. But with a million doctors and only 400 of us, it's kind of hard to overturn that perception." Numerous studies show the perception's pervasiveness. Appearing with Hutchinson at the press conference was preeminent pain researcher Russell K. Portenoy, MD, citing results of a recent survey of 1,400 New York physicians conducted by the state's Department of Health: nearly 40 percent of doctors admitted to changing their prescribing behavior for fear of DEA and other regulatory scrutiny.

The Southern California Cancer Pain Initiative's Ferrell cites DEA and other law enforcement's opposition to a state bill in 2000 that would have revoked the state's multiple-copy prescription law. (The state has an electronic monitoring system; see p. 6). Ferrell joins many others in applauding the DEA's involvement in the statement, but she expresses the medical community's wait-and-see attitude: "There's just no detail about how these promises are going to be kept. The DEA needs to articulate how it will really help break down the ridiculous, insane barriers to patient access to pain management." ■

"We don't want to cause patients who have legitimate needs for these medications to be discouraged or afraid to use them. And we don't want to restrict doctors and pharmacists from providing these medications when appropriate."

Asa Hutchinson, Administrator,
Drug Enforcement Administration

For the full text of the Joint Statement and a list of signatories, go to: www.medsch.wisc.edu/painpolicy/dea01.htm

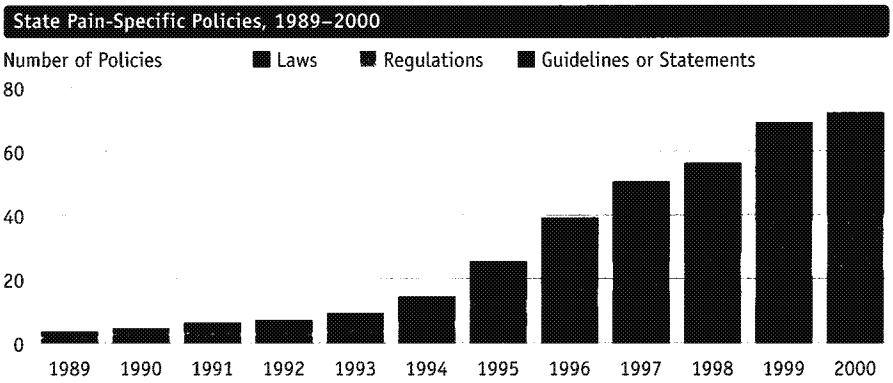
Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

As of May 8, 2002, 42 health care organizations joined the DEA in endorsing this statement.

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need. Both health care professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical. Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve.

A Roundup of Recent Pain Policy Advances and Trends

Three types of policies affect pain management: state and federal law, state and federal regulations and guidelines or standards adopted or instituted by state and federal organizations that license practitioners or accredit institutions. What follows are explorations of the major state-level policy trends or actions affecting pain management at the end of life that have emerged in the past two years.



Source: University of Wisconsin Pain and Policy Studies Group/WHO Collaborating Center, 2000

Unprecedented Boom in State Pain Policy

State medical boards—not legislatures—are charged with upholding the standard of care among a state's physicians. So pain policy experts say medical board pain treatment guidelines are one of the most effective ways to address doctors' fear of treating pain.

The Federation of State Medical Boards' model guidelines on the use of opioids in pain management, released in May 1998, are often cited as an example of progressive pain policy because they:

- accept opioids' medical importance
- reject quantity and chronicity of prescribing as regulatory measurements of good medical practice—embracing instead patients' needs and quality of follow-up and documentation
- state that the medical board will not discipline a physician for failing to adhere strictly to the guidelines if good cause is shown for deviation

The DEA was quick to endorse the model guidelines. In the past two years, an unprecedented number of state medical boards have adopted these guidelines (see chart above). But the PPSG, which closely monitors state pain policy, is concerned that this trend may have reached a plateau, and that those states that haven't already adopted the guidelines should consider doing so, says Joranson.

Moves Toward Electronic Prescription Monitoring

One of the best ways to prevent diversion caused by doctor-shopping, some pain policy experts say, is for a state to institute an electronic system for pharmacies to transfer prescription information to regulatory agencies. An authorized agency can then monitor whether individuals are receiving opioid prescriptions from multiple physicians. Such a monitoring system is less invasive and expensive than special forms, which are onerous to physicians and patients.

California Assemblywoman Helen Thomson (D) sponsored a bill in 2000 that would have shifted the oversight of prescriptions entirely from a triplicate-form system to a computerized system already up and running (see *State Initiatives in End-of-Life Care*, Issue 9, p. 4). But due to strong opposition from the state attorney general and other law enforcement agencies, the bill was watered down and the triplicate system retained. "The regulatory agencies, including the DEA, made sure that this bill failed," says the SCCPI's Betty Ferrell. "They used political means to sabotage it. It was supported by both legislative chambers, and 30 major consumer groups advocated for it, but after it passed, the governor vetoed it because of pressure from law enforcement."

Kay Felt, JD, a Michigan attorney and member of the Michigan Commission on End-of-Life Care and the governor's Advisory Committee on Pain and Symptom Management, says a 2001 commission study showed any type of "special" monitoring reduced physicians' likelihood of treating pain. The commission last year recommended the total disbanding of the state's Official Prescription Program, which requires "a huge, monstrous prescription pad you can't carry in your pocket," says Felt. The special prescription-form law "interferes with medical treatment of pain. . . . Physicians have the feeling that somehow they're scrutinized—even though they're actually not. Pharmacies are very reluctant to carry or dispense these medications. Plus, the program costs $800,000 per year to administer—and *nothing is done with the information*," says Felt.

Currently 16 states have electronic programs, but seven of those, including Michigan, still require some special form. She says the commission hopes the state will eventually use only electronic monitoring. "There's now legislation in the house to do that," Felt says of Michigan.

Persistent Regulatory Scrutiny Continues to Discourage Docs

To understand why physicians worry so much about regulatory scrutiny, the case of Joan Lewis, MD, is illustrative. Lewis is a prominent Albuquerque pain specialist who helped write New Mexico's Pain Relief Act. But her credentials and experience with pain treatment did not prevent her from being investigated in 2001 by the state board of medical examiners on six counts of "injudicious prescribing" of opioids to patients with chronic non-cancer pain.

The investigation went forward even though Lewis scrupulously adhered to state policy by monitoring her patients closely, even asking them also to document their use of the medications she prescribed. Many of her patients—including four of the six whose cases were cited in the investigation—came forward in her support, as did other prominent physicians, by contributing friend of the court briefs on Lewis's behalf.

Even though Lewis had co-authored the pain management guidelines used by the medical board to evaluate physicians' prescribing actions—including Lewis's own—the board apparently found sufficient evidence of "injudicious prescribing" to consider revoking or suspending her license. The state attorney general personally reviewed Lewis's case and declined to prosecute. The medical board never held a hearing, so no findings were ever issued against Lewis. But Lewis was not off the hook. In exchange for stopping its investigation, the board of medical examiners has required her to practice under supervision for two years and obtain more training in pain management out of state.

Not surprisingly, pain treatment advocates, including those working in end-of-life care, are concerned that this board's attitude not be permitted to touch off a wildfire of scrutiny of the 1,200 pain specialists throughout the country, who are often the only doctors in their communities willing to treat pain aggressively. Three organizations filed amicus briefs in Lewis's support: the Compassion in Dying Federation and the Americans for Better Care of the Dying, both national nonprofit groups supporting better end-of-life care, including improved pain care; and the American Academy of Pain Management, North America's largest multidisciplinary pain management organization. "There has been a series of other cases across the country, of physicians charged with overprescribing," says the SCCPI's Betty Ferrell. "There has been a series of lawsuits and medical board investigations. They involve enormous expense and time for doctors. Of course, every one of these cases has an enormous chilling effect."

In California, a Physician Is Sued for Pain Undertreatment

On the other side of the coin, there is the case of Dr. Wing Chin, a California physician found guilty in 2001 of elder abuse for failing to give a dying lung cancer patient adequate pain medication. When the patient's family's complaints about Chin's practice were ignored by the state medical board, the family filed a civil suit—and won $1.5 million.

Pain treatment advocates see both benefits and problems with using lawsuits to influence practice. "I'm not enthusiastic about lawsuits, but such a case surely does make physicians sit up and take notice," says June Dahl. Ferrell notes that a lawsuit allows the public to take control: "A lawsuit speaks to us in a different way than a published paper, a set of guidelines, or a medical board action. It says that this is no longer a professional issue—it's a social issue, a public issue."

Susan Tolle, MD, director of the Center for Ethics in Health Care in Oregon, says lawsuits feel more like a bolt of lightning, while board discipline "feels more like a consistent

Continues on page 8

State Initiatives *Kicks Off New Audio Series*

Heart to Heart: Improving Care for the Dying through Public Policy is a new four-part series of half-hour audio documentaries for policymakers and professionals. The series offers policy solutions to improve the quality of end-of-life care given by hospitals, nursing homes, physicians, and other providers.

Part I: Pain Management, the series' first program, has been released simultaneously with this brief and can be ordered using the order information below. Featured in this first program are many of the leading experts in pain management and public policy quoted in this brief, such as DEA Administrator Asa Hutchinson and PPSG Director David Joranson, and others, including Richard Payne, MD, chair of Sloan-Kettering's Pain and Palliative Care Service, and Joanne Lynn, MD, president of Americans for Better Care of the Dying.

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Opioid Diversion: A Renewed Call for a Balanced Drug Policy

Continued from page 4

Yet states are proposing policies to combat OC diversion that include

- limiting OC prescribing privileges to pain specialists
- limiting dispensing of OC to designated pharmacies
- making Schedule II opioids the treatment of "last resort" for chronic pain
- taking OC off the market
- making prescription-form theft a distinct offense punishable as a third-degree felony

According to the litmus test, the first four do not meet the criteria for balanced policy, while the last—proposed by Pennsylvania Attorney General Mike Fisher—does.

A Perennial Problem

It has been suggested that abuse of prescription medication is generally on the rise. Joranson's team is studying the DAWN data from 2000 to see whether the rate at which prescription pain medication is abused has any correlation to an apparent increase in the past four or five years in medical use of opioids to treat pain.

The best that can be hoped for, some pain policy experts suggest, is simply to reduce diversion. "We will never be able to completely eliminate the diversion and abuse of scheduled prescription medications unless we ignore our responsibilities to patients in pain and take the drugs off the market," says June Dahl. While a solution to this latest crisis is being sought, she says, dying patients are the last who should suffer undue consequences. "There is no evidence that diversion by pain patients is a significant problem," Dahl says. "For cancer patients and people at the end of life, diversion is simply not an issue." ■

A Roundup of Recent Pain-Policy Advances and Trends

Continued from page 7

pattern." The first—and so far, only—physician to be disciplined by a medical board for undertreatment of pain was in Oregon in 1999, and Tolle says, "The minute the board's action came out, the medical students fixated on it. It was an 'ah-ha' moment for these young doctors—that undertreatment of pain could be a standard of practice, too. That there is a certain floor in pain management, below which you're unacceptable." But Tolle says civil suits move oversight of opioid use away from the infrastructure of policy and into the capricious arena of the civil courts. "In Oregon, you can get investigated if you go too far in either direction, and the goal is balance," she believes. "In California, there's only one way you appear to get in trouble—their board disciplines docs only for overprescribing. So, California doctors see that the safe path is to prescribe less." In other words, to undertreat pain.

The Joint Commission's Recent Call to Action

In 2000, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) released new pain treatment standards for hospitals, nursing homes, home-health agencies, and other institutions that provide direct patient care. One of the standards requires accredited facilities to assess pain in all patients. The first data on these standards' clinical results are starting to roll in, but have not been analyzed yet.

"The pain standard is really critical because it means that accredited facilities can no longer ignore pain," Dahl says. "It puts pain on every institution's radar screen. These standards affect all patients in pain and thus should have a major impact on the quality of care for those who are dying." ■

Information about the Series

"Pain Management—An Update: The Need for Balance in Controlled Substances Policy" is the fourteenth in a series of briefs profiling promising new policies and practices in end-of-life care.

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United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

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PRESCRIPTION DRUGS

State Monitoring Programs May Help to Reduce Illegal Diversion

Statement of Marcia Crosse
Director, Health Care—Public Health and Military Health Care Issues

GAO-04-524T

March 4, 2004

PRESCRIPTION DRUGS

State Monitoring Programs May Help to Reduce Illegal Diversion

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-04-524T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the nation's battle against drug abuse. Diversion can include such activities as prescription forgery and "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions. The most frequently diverted prescription drugs are controlled substances that are prone to abuse, addiction, and dependence, such as hydrocodone (the active ingredient in Lortab and many other drugs) and oxycodone (the active ingredient in OxyContin and many other drugs).

Some states use prescription drug monitoring programs to control illegal diversion of prescription drugs that are controlled substances.

GAO was asked to examine (1) how state monitoring programs compare in terms of their objectives and operation and (2) the impact of state monitoring programs on illegal diversion of prescription drugs.

This testimony is based on GAO's report, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (May 17, 2002). In that report, the programs in Kentucky, Utah, and Nevada were selected for more in-depth study because they were the most recently established programs at the time.

www.gao.gov/cgi-bin/getrpt?GAO-04-524T

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

What GAO Found

GAO found that the 15 state monitoring programs in place in 2002 differed in their objectives and operation. The programs were intended to facilitate the collection, analysis, and reporting of information about the prescribing, dispensing, and use of controlled substances. They provided data and analysis to state law enforcement and regulatory agencies to assist in identifying and investigating activities potentially related to illegal drug diversion. The programs could be used by physicians to check a patient's prescription drug history to determine if the individual was doctor shopping to seek multiple controlled substances. Some programs also offered educational programs for the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. The programs varied primarily in terms of the specific drugs they covered and the type of state agency in which they were housed. Some programs covered only those prescription drugs that are most prone to abuse and addiction, whereas others provided more extensive coverage. In addition, most programs were administered by a state law enforcement agency, a state department of health, or a state board of pharmacy.

GAO also found that state monitoring programs may have realized benefits in their efforts to reduce drug diversion. These included improving the timeliness of law enforcement and regulatory investigations. Each of the three states studied reduced its investigation time by at least 80 percent. In addition, law enforcement officials told GAO that they view the programs as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilization histories based on monitoring program data. For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today and thank you for the opportunity to discuss our work on state prescription drug monitoring programs and their use in addressing the diversion of prescription drugs for illegal use.

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the nation's battle against drug abuse.[1] Diversion activities can include "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, prescription forgery, and purchasing drugs from Internet pharmacies without valid prescriptions. The most frequently diverted prescription drugs are controlled substances[2] that are prone to abuse, addiction, and dependence,[3] such as hydrocodone (the active ingredient in Lortab and many other drugs), diazepam (Valium), methylphenidate (Ritalin), and oxycodone (the active ingredient in OxyContin and many other drugs). According to the Drug Enforcement Administration (DEA), increases in the extent of prescription drug abuse and in emergency room visits related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide.

Some states operate prescription drug monitoring programs as a means to control the illegal diversion of prescription drugs. My remarks today will focus on (1) how state monitoring programs compare in terms of their objectives and operation and (2) the overall impact of state monitoring programs on illegal diversion of prescription drugs. My comments are based on our May 2002 report on state monitoring programs and their

[1]Office of Drug Control Policy, "U.S. Drug Prevention, Treatment, Enforcement Agencies Take on 'Doctor Shoppers', 'Pill Mills'," Mar. 1, 2004, www.whitehousedrugpolicy.gov (downloaded Mar. 2, 2004).

[2]Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and safety or dependence liability.

[3]According to the National Institute on Drug Abuse, addiction is a chronic, relapsing disease, characterized by compulsive drug seeking and use and by neurochemical and molecular changes in the brain, whereas physical dependence is an adaptive physiological state that can occur with regular drug use and results in withdrawal symptoms when drug use is discontinued.

usefulness as a tool for reducing diversion.[3] For that report we reviewed information from DEA and the National Alliance for Model State Drug Laws on the features of existing programs. To gain a more in-depth understanding of these programs and the challenges they face, we also studied the programs in Kentucky, Nevada, and Utah. We selected these three states because at the time they had the most recently established programs.

In brief, we found that 15 states operated monitoring programs in 2002 as a means to control the illegal diversion of prescription drugs that are controlled substances.[5] Although these programs were all intended to facilitate the collection, analysis, and reporting of information about the prescribing, dispensing, and use of controlled substances, they differed in their objectives and operation. They all provided data and analysis to state law enforcement and regulatory agencies in order to assist in identifying and investigating activities potentially related to the illegal prescribing, dispensing, and procuring of controlled substances. Further, some programs could be used by physicians to check a patient's prescription drug history to determine if the individual may have been doctor shopping to seek multiple controlled substances. Some programs also offered educational programs for the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. The operation of the monitoring programs varied primarily in terms of the specific drugs they covered and the type of state agency in which they were housed. Some programs covered only those prescription drugs that are most prone to abuse and addiction, whereas others provided more extensive coverage. In addition, most programs were administered by a state law enforcement agency, a state department of health, or a state board of pharmacy.

We found that state monitoring programs realized benefits in their efforts to reduce drug diversion. These included improving the timeliness of law enforcement and regulatory investigations. Each of the three states we

[4]For more details on these programs, see U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D.C.: May 17, 2002).

[5]The 15 states were California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington. In 1998, West Virginia terminated its monitoring program, but began operating a program again in 2003, bringing the total of state programs to 16. In addition, Virginia began operating a pilot program in the southwestern part of the state in fall 2003.

studied reduced its investigation time by at least 80 percent. In addition, law enforcement officials told us that they view the programs as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilization histories based on monitoring program data. For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states.

Background

The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities. DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multibillion-dollar illicit market nationwide. One recent example of this growing diversion problem concerns the controlled substance oxycodone, the active ingredient in over 20 prescription drugs, including OxyContin, Percocet, and Percodan. OxyContin is the number one prescribed narcotic medication for treating moderate-to-severe pain in the United States.[6] Currently, a single 20-milligram OxyContin tablet legally selling for about $2 can be sold for as much as $25 on the illicit market in some parts of Kentucky.

Combating the illegal diversion of prescription drugs while ensuring that the pharmaceuticals remain available for those with legitimate medical need involves the efforts of both federal and state government agencies. The Controlled Substances Act of 1970[7] provides the legal framework for the federal government's oversight of transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels. The states address these issues through their regulation of the practice of medicine and pharmacy.

[6]U.S. General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (Washington, D.C.: Dec. 23, 2003).

[7]Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. No. 91-513, §§100 *et seq.*, 84 Stat. 1236, 1242 *et seq.*).

Controlled Substances Act

The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances.[8] Controlled substances are classified by DEA into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD and PCP—have a high potential for abuse and no currently accepted medical use. Schedule II drugs—including methylphenidate (Ritalin) and opiates such as hydrocodone, morphine, and oxycodone—have a high potential for abuse among drugs with an accepted medical use and may lead to severe psychological and physical dependence. Drugs on schedules III through V have accepted medical uses and successively lower potentials for abuse and dependence. Schedule III drugs include anabolic steroids, codeine, hydrocodone in combination with aspirin or acetaminophen, and some barbiturates. Schedule IV contains such drugs as the antianxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All scheduled drugs except those in schedule I are legally available to the public with a prescription.[9]

Under the act, DEA provides legitimate handlers of controlled substances—including manufacturers, distributors, hospitals, pharmacies, practitioners, and researchers—with registration numbers, which are used in all transactions involving controlled substances. Registrants must comply with a series of regulatory requirements relating to drug security and accountability through the maintenance of inventories and records. Although all registrants, including pharmacies, are required to maintain records of controlled substance transactions, only manufacturers and distributors are required to report their transactions involving schedule II drugs and schedule III narcotics, including sales to the retail level, to DEA. The data provided to DEA are available for use in monitoring the distribution of controlled substances throughout the United States, in identifying retail-level registrants that received unusual quantities of controlled substances, and in investigations of illegal diversions at the manufacturer and wholesaler levels. Although data are reported to DEA regarding purchases by pharmacies, the act does not require the reporting of dispensing information by pharmacies at the patient level to DEA.

[8]Section 201, classified to 21 U.S.C. § 811.

[9]Some schedule V drugs that contain limited quantities of certain narcotic and stimulant drugs are available over the counter without a prescription.

State Regulation of the Practice of Medicine and Pharmacy

State laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals. State medical practice laws generally delegate the responsibility of regulating physicians to state medical boards, which license physicians and grant them prescribing privileges.[10] In addition, state medical boards investigate complaints and impose sanctions for violations of the state medical practice laws. States regulate the practice of pharmacy based on state pharmacy practice acts and regulations enforced by the state boards of pharmacy. The state boards of pharmacy are also responsible for ensuring that pharmacists and pharmacies comply with applicable state and federal laws and for investigating and disciplining those that fail to comply. According to the National Association of Boards of Pharmacy, all state pharmacy laws require that records of prescription drugs dispensed to patients be maintained and that state pharmacy boards have access to the prescription records.

State Monitoring Programs Varied in Objectives and Operation

State prescription drug monitoring programs varied in their objectives and operation. While all programs were intended to help law enforcement identify and prevent prescription drug diversion, some programs also included education objectives to provide information to physicians, pharmacies, and the public. Program operation also varied across states, in terms of which drugs were covered and how prescription information was collected. Which agency, such as a pharmacy board or public health department, was given responsibility for the program also varied across states. Additionally, methods for analyzing the data to detect potential diversion activity differed among state programs.

State monitoring programs are intended to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of prescription drugs within a state. The first state monitoring program was established in California in 1940, and the number of programs has grown slowly. We reported that the number of states with programs has grown from 10 in 1992 to 15 in 2002; the number of programs stands at 16 in 2004.

[10]The types of practitioners who prescribe drugs and may be monitored by a state program vary among states. Physicians are the majority of covered practitioners, but in most states many nonphysicians who also have prescribing authority may be covered, including physician assistants, dentists, optometrists, podiatrists, veterinarians, and certain types of nurses, such as nurse practitioners and advanced practice nurses.

We found that state programs varied in their objectives. All states used monitoring programs primarily to assist law enforcement in detecting and preventing drug diversion, and but some also used the programs for educational purposes. Programs assisted law enforcement authorities both by providing information in response to requests for assistance on specific investigations and by referring matters to law enforcement officials when evaluations of program data revealed atypical prescribing or dispensing patterns that suggested possible illegal diversion. The programs evaluated prescribing patterns to identify medical providers who may have been overprescribing and inform them that their patterns were unusual. They also identified patients who may have been abusing or diverting prescription drugs and provided this information to practitioners. For example, the programs in Nevada and Utah sent letters to physicians containing patient information that could signal potential diversion activity, including the number and types of drugs prescribed to the patient during a given time period and the pharmacies that dispensed the drugs. Monitoring programs have also been used to educate physicians, pharmacies, and the public about the existence and extent of diversion, diversion scams, the drugs most likely to be diverted by individuals, and ways to prevent drug diversion.

Monitoring programs also differed in operational factors, some of which have cost implications. These factors included the choice of controlled substance schedules monitored, approaches to analyzing and using data, computer programming choices, number and type of staff and contractors, turnaround times and report transmittal methods, and number and type of requests for information.

State programs varied in the controlled substances they covered, in part because of differences in available resources and other state-specific factors such as level of drug abuse. Two of the states we studied—Kentucky and Utah—covered schedules II through V. These states' program officials told us that covering those schedules allowed them flexibility to respond if drugs on other schedules became targets for diversion. Most experts agree that covering all controlled substance schedules prevents drug diverters from avoiding detection by bypassing schedule II drugs and switching to drugs in other schedules.

States used different approaches to analyze the prescription information they received. A few states used a proactive approach, routinely analyzing prescription data collected by the programs to identify individuals, physicians, or pharmacies that had unusual use, prescribing, or dispensing patterns that could suggest potential drug diversion, abuse, or doctor

shopping. Trend analyses were shared with appropriate entities, such as law enforcement, practitioners, and regulatory and licensing boards. In contrast, most state programs generally used the prescription data in a reactive manner to respond to requests for information. These requests may have come from physicians or from law enforcement or state officials based on leads about potential instances of diversion. According to state program officials, most programs operated in a reactive fashion because of the increased amount of resources required to operate a proactive system.

Some state programs had electronic reporting systems, while others were paper-based. If data are reported electronically, there are ongoing computer maintenance and programming choices and their attendant costs. Similarly, some state programs engaged private contractors to collect and maintain the data, while others did so in-house. If a private contractor collects the raw data from dispensers and converts them to a standardized format, the program pays annual contracting costs for database maintenance. Kentucky and Nevada privately contracted with the same company to collect data for their program databases. Utah, in contrast, collected and maintained drug dispensing data in-house, using its own software and hardware.

The number and type of staff a state chose to operate its monitoring program also varied. In 2002, Kentucky's program employed four full-time and four part-time staff to help ensure the accuracy of its reports, including a pharmacist-investigator who reviewed each report before it was sent. Nevada's program operated with one employee because a private contractor collected the data. In contrast, in 2002 Utah's program, with three full-time employees and no private contractor, had one program administrator who collected all dispensing data, converted them to a standardized format for monitoring, and maintained the database. The two other staff answered requests.

If the program seeks to provide more timely responses to report requests, such as same-day responses, the costs involved in returning the response to the requester may increase. For example, in 2001 Kentucky spent up to $12,000 in 1 month for faxing reports. Monitoring program officials from Kentucky, Nevada, and Utah told us in 2002 that they estimated 3- to 4-hour turnaround times for program data requests, and all mainly used faxing, rather than more costly mailing, to send reports to requesters. Same-day responses may be preferable for physicians who want the prescription drug history for a patient being seen that day and for law enforcement users who need immediate data for investigations of suspected illegal activity.

As users become more familiar with the benefits of monitoring program report data, requests for information and other demands on the programs may increase. In Kentucky, Nevada, and Utah, use had increased substantially, mostly because of an increase in the number of requests by physicians to check patients' prescription drug histories. In Kentucky, these physician requests increased from 28,307 in 2000, the first full year of operation, to 56,367 in 2001, an increase of nearly 100 percent. Law enforcement requests increased from 4,567 in 2000 to 5,797 in 2001, an increase of 27 percent. Similarly, Nevada's requests from all authorized users also increased—from 480 in 1997, its first full year, to 6,896 in 2001, an increase of about 1,300 percent.

Additionally, as drug marketing practices change and monitoring programs mature, the operational needs may shift as well. For example, states face new challenges with the advent of Internet pharmacies, because they enable pharmacies and physicians to anonymously reach across state borders to prescribe, sell, and dispense prescription drugs without complying with state requirements.[11] In addition, if users want program reports to reflect more timely information, dispensing entities would have to report their data at the time of sale, rather than submitting data biweekly or monthly, to capture the most recent prescription dispensing. If users want to be alerted if a certain drug, practitioner, or pharmacy may be involved in a developing diversion problem, programs would have to initiate periodic data analysis to determine trends or patterns. Such program enhancements would entail additional costs, however, including costs for computer programming, and data analysis.

States that are considering establishing or expanding a monitoring program face a variety of other challenges. One challenge is the lack of awareness of the extent to which prescription drug abuse and diversion is a significant public health and law enforcement problem. States also face concerns about the confidentiality of the information gathered by the program, voiced by patients who are legitimately using prescription drugs and by physicians and pharmacists who are legitimately prescribing and dispensing them. Another challenge states face is securing adequate

[11]For more details on Internet pharmacies, see U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69 (Washington, D.C.: Oct. 19, 2000).

funding to initiate and develop the program and to maintain and modify it over time.[12]

State Monitoring Programs Have Helped Shorten Investigation Times and May Reduce Illegal Drug Diversion

We found that states with monitoring programs have experienced considerable reductions in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. We also found that the presence of a monitoring program in a state may help reduce illegal drug diversion there, but that diversion activities may increase in contiguous states without programs.

The ability of the programs to focus law enforcement and regulatory investigators who are working on suspected drug diversion cases on specific physicians, pharmacies, and patients who may be involved in the alleged activities is crucial to shortened investigation time and improvements in productivity. States that do not have programs must rely on tips from patients, practitioners, or law enforcement authorities to identify possible prescription drug abuse and diversion. Following up on these leads requires a lengthy, labor-intensive investigation. In contrast, the programs can provide information that allows investigators to pinpoint the physicians' offices and pharmacies where drug records must be reviewed to verify suspected diversion and thus can eliminate the need to search records at physicians' offices and pharmacies that have no connection to a case.

In each of the three states we studied, state monitoring programs led to reductions in investigation times. For example, prior to implementation of Kentucky's monitoring program, its state drug control investigators took an average of 156 days to complete the investigation of alleged doctor shoppers. Following the implementation, the average investigation time dropped to 16 days, or a 90 percent reduction in investigation time. Similarly, Nevada reduced its investigation time from about 120 days to

[12]Federal grants are available to states to establish new monitoring programs and to enhance existing programs under the Harold Rogers Prescription Drug Monitoring Program. DEA's Office of Diversion Control, in collaboration with the Department of Justice's Bureau of Justice Assistance, provides grants to states to establish new programs and to enhance existing monitoring programs through the Harold Rogers Prescription Drug Monitoring Program. The fiscal year 2003 grantees are Alabama, Florida, Maine, New Mexico, and Wyoming for new programs, and California, Idaho, Nevada, and New York for enhanced programs. The grantees in fiscal year 2002 were Ohio, Pennsylvania, Virginia, and West Virginia for new programs, and California, Kentucky, Massachusetts, Nevada, and Utah for enhanced programs.

about 20 days, a reduction of 83 percent, and a Utah official told us that it experienced an 80 percent reduction in investigation time.

Officials from Kentucky, Nevada, and Utah told us in 2002 that their programs may have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increased number of program reports were being used by physicians to check the prescription drug use histories of current and prospective patients when deciding whether to prescribe certain drugs that are subject to abuse. Law enforcement officials told us that they view these drug history checks as initial deterrents— a front-line defense—to prevent individuals from visiting multiple physicians to obtain prescriptions, because patients are aware that physicians can review their prescription drug history. For an individual who may be seeking multiple controlled substance prescriptions, the check allows a physician to analyze the prescription drug history to determine whether drug treatment appears questionable, and if so, to verify it with the listed physicians. In Kentucky, a physician could request a drug history report on the same day as the patient's appointment, and usually received the report within 4 hours of the request. In 2002, Kentucky's program typically received about 400 physician requests daily, and provided data current to the most recent 2 to 4 weeks.

The presence of a monitoring program may also have an impact on the prescribing of drugs more likely to be diverted. For example, DEA ranked all states for 2000 by the number of OxyContin prescriptions per 100,000 people.[13] Eight of the 10 states with the highest numbers of prescriptions—West Virginia, Alaska, Delaware, New Hampshire, Florida, Pennsylvania, Maine, and Connecticut—had no monitoring programs, and only 2 did—Kentucky and Rhode Island. Six of the 10 states with the lowest numbers of prescriptions—Michigan, New Mexico,[14] Texas, New York, Illinois, and California—had programs, and 4—Kansas, Minnesota, Iowa, and South Dakota—did not.

[13]OxyContin, Hearings Before the Subcommittee on the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies, House Committee on Appropriations, 107th Cong. Part 10., pp. 21, 22 (2001) (Statement of Asa Hutchinson, Administrator of the Drug Enforcement Administration).

[14]New Mexico's monitoring program was terminated in June 2000.

Another indication of the effectiveness of a monitoring program is that its existence in one state appears to increase drug diversion activities in contiguous states without programs. When states begin to monitor drugs, drug diversion activities tend to spill across boundaries to states without programs. One example is provided by Kentucky, which shares a boundary with seven states, only two of which had programs in 2002—Indiana and Illinois. As drug diverters became aware of the Kentucky program's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states. OxyContin diversion problems worsened in Tennessee, West Virginia, and Virginia—all contiguous states without programs—because of the presence of Kentucky's program, according to a 2001 joint federal, state, and local drug diversion report.[15]

Concluding Observations

Although monitoring programs can enhance the ability of states to detect and deter illegal diversion of prescription drugs, the number of states with such programs has grown only slightly over the past 12 years from 10 in 1992 to 16 in 2004. A lack of awareness of the magnitude of the problem; concerns about confidentiality on the part of patients, physicians, pharmacists, and legislators; and difficulty in accessing funding have kept the numbers of monitoring programs low. Cooperative efforts at the state and national levels are seeking to overcome these challenges and increase the number of states with programs.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Contact and Acknowledgments

For more information regarding this testimony, please contact Marcia Crosse at (202) 512-7119. Individuals making key contributions to this testimony include Martin T. Gahart, Roseanne Price, and Opal Winebrenner.

[15]Appalachia High Intensity Drug Trafficking Area Investigative Support Center, with the assistance of the National Drug Intelligence Center, *The OxyContin Threat in Appalachia* (London, Ky.: Aug. 2001).

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